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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/663,787	09/17/2003	Amy S. Giuliano	22373.00	2977

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EXAMINER

DEAK, LESLIE R

ART UNIT PAPER NUMBER

3761

DATE MAILED: 11/01/2005

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary

Application No.

10/663,787

Applicant(s)

GIULIANO ET AL.

Examiner

Leslie R. Deak

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-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 17 September 2003.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-12 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 1-12 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☒ The drawing(s) filed on 17 September 2003 is/are: a) ☒ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
- ☐ Certified copies of the priority documents have been received.
 - ☐ Certified copies of the priority documents have been received in Application No. _____.
 - ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|--|---|
| 1) <input checked="" type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413)
Paper No(s)/Mail Date. _____ |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | 5) <input type="checkbox"/> Notice of Informal Patent Application (PTO-152) |
| 3) <input checked="" type="checkbox"/> Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08)
Paper No(s)/Mail Date <u>9/17/03</u> . | 6) <input type="checkbox"/> Other: _____ |

DETAILED ACTION

Claim Rejections - 35 USC § 102

1. The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

2. Claims 1-6, 11, and 12 are rejected under 35 U.S.C. 102(b) as being anticipated by US 6,179,823 to Niedospial, Jr.

Niedospial discloses the invention as claimed by applicant in the disclosure and the figures. Specifically, Niedospial discloses a pouch-shaped medical container 310 with an interior space that may hold a fluid 355 (see FIG 18, column 14). The bag further comprises a hole or handle portion 317 for hanging the bag at the top of the container and access ports 400, 420, 431 located at the bottom of the bag. Port 420 may be used as a spike access or outlet port, while port 431 comprises an end 32 that receives universal adapter 30. Universal adapter 30 comprises a resilient valve member 90 that seals the fluid channel defined by the internal wall 52 of the universal connector 30 (see column 8, lines 40-46). The diaphragm or valve member 90 deforms when engaged with a tip of an access device (see FIGS 7A, 7B) and reseals when the access device (which may be a syringe) is removed (see column 10, lines 17-25, column 11, lines 5-20).

Applicant's recitations drawn to what the device is "adapted to" do are not afforded patentable weight. It has been held that the recitation that an element is

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“adapted to” perform a function is not a positive limitations but only requires the ability to so perform. It does not constitute a limitation in any patentable sense. In re Hutchison, 69 USPQ 138.

With regard to claim 4, Niedospial discloses the bag and ports substantially as claimed. In particular, Niedospial discloses a solution bag as described above, including an outlet port. The outlet port or spike access 420 includes a tubular extension (generally 420) protruding from the bag with an inlet end connected to the pouch, and a puncturable seal 422 (see FIG 18). Niedospial does not specifically disclose a flange, but the bottom portion (not labeled, but generally at 318, 320) of bag 310 connects with port 420, creating a shoulder or flange (i.e., it is regarded as the recited flange):

With regard to claims 7-10 drawn to the threading and luer connectors on the inlet valve, Niedospial discloses that universal connector 30 comprises ring 42 that serves as a male thread or luer connector (see column 8, lines 16-26). Further, Niedospial discloses that the connector 30 may engage with a luer connector (see column 7, lines 60-65, column 10, lines 17-20). In an alternate embodiment, connector 30 comprises a luer adapter 120 with internal threads 142, providing a female luer connector.

Claim Rejections - 35 USC § 102/103

3. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the

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invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

4. Claim 12 is rejected under 35 U.S.C. 102(b) as anticipated by or, in the alternative, under 35 U.S.C. 103(a) as obvious over US 6,179,823 to Niedospial, Jr.

With regard to applicant's claim 12 drawn to the method of forming or manufacturing the solution bag, the method of forming the device is not germane to the issue of the patentability of the device itself. Therefore, this limitation has not been given patentable weight.

In the alternative, Niedospial discloses all the elements of the device as claimed by applicant, but fails to disclose that the device is manufactured as a single unit. It would have been obvious to one having ordinary skill in the art at the time the invention was made to form the solution bag as a single unit, since forming in one piece an article that has formerly been formed in two pieces and put together involves only routine skill in the art. See MPEP 2144.04.

Conclusion

5. The prior art made of record and not relied upon is considered pertinent to applicant's disclosure:

- a. US 5,645,538 Richmond
 - i. Needleless valve for IV infusion
- b. US 6,491,668 Paradis
 - ii. Needleless fluid transfer valve
- c. US 6,602,239 Rönnekleiv

- iii. Infusion bag with valved connector
- d. US 6,855,138 Tsai
- iv. Valved connector for IV tube

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Leslie R. Deak whose telephone number is 571-272-4943. The examiner can normally be reached on M-F 7:30-5:00, every other Friday off.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Tanya Zalukaeva can be reached on 571-272-1115. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).



Leslie Deak
Patent Examiner
Art Unit 3761
26 October 2005